

The Examiner has rejected Claims 10 and 23-28 under 35 U.S.C. § 112, second paragraph, for certain reasons set forth on pages 3 and 4 of the Office action that show that the rejection is merely based on obvious typographical or clerical errors. Applicants appreciate that the Examiner has brought these inadvertent errors to their attention and have addressed them by the present amendment. Since the amendment obviates the rejection, it is respectfully asked that the Examiner withdraw the rejection.

The Examiner also rejects Claims 1, 5, 20 and 29 (now Claims 1, 5, 29 and 31) under 35 U.S.C. § 102 (b) as being anticipated by Hatton *et al.* (U.S. Patent No. 5,232,940) or Hatton *et al.* (WO87/03781) for reasons set forth on page 5 of the Office action. Without comment on the merits of the rejection but to expedite matters towards an allowance, Applicants have amended the compound and composition Claims 1 and 29 to include the proviso that was originally recited in non-rejected Claims 2 and 30. The proviso effectively removes from the scope of Claims 1 and 29 any generic compounds that are unintentionally overlapping with the compounds described in the cited references.

Insofar as Claim 20 is concerned, the dependent claim has been rewritten as a new independent Claim 31 that does not require the same proviso in generic Claims 1 and 29 to overcome the cited references. Specifically, the rejection of Claim 31 based on anticipation fails because the requisite identity of invention is lacking in the evidence at hand. There is no disclosure of the particular veterinary pour-on composition and recited ingredients of a spreading oil, an aliphatic or aromatic hydrocarbon, mono or polyhydric alcohol, a C<sub>1</sub>-C<sub>10</sub> alkyl ketone, or a mixture thereof in either Hatton *et al.* document.

In view of the amendment and the above comments, Applicants respectfully request that the rejection of Claims 1, 5, 29 and 31 under 35 U.S.C. § 102 (b) be withdrawn.

The Examiner further rejects Claims 1-10, 20-23 and 26-30 (now Claims 1, 3-10, 26-29 and 31-35) under 35 U.S.C. § 102 (e) as being anticipated by Furch *et al.* (WO03/02922) for reasons set forth on page 6 of the Office action. Without comment on the merits of the rejection but to advance prosecution towards the allowance, Applicants have added a proviso to the generic Claims 1 and 29 to carve out the specific compounds that are unintentionally overlapping with the compounds of Furch *et al.* Also, the overlapping species have been canceled from Claims 10 and 26.

With respect to Claims 20-23, now presented as Claims 31-35, the rejection based on anticipation is not justified. Furch *et al.* do not describe the specific veterinary pour-on composition recited in the independent Claim 31. Therefore, the claimed invention is not anticipated by the cited reference.

In view of the amendment and the above comments, Applicants respectfully request that the rejection of Claims 1, 3-10, 26-29 and 31-35 under 35 U.S.C. § 102 (e) be withdrawn.

Additionally, the Examiner rejects Claims 1-10 and 20-30 (now Claims 1, 3-10, 24-29 and 31-35) under 35 U.S.C. § 103(a) as being obvious over Hatton *et al.* (U.S. Patent No. 5,232,940), Hatton *et al.* (WO87/03781) and Furch *et al.* (WO03/02922), each taken alone or in combination with each other, for reasons set forth on pages 7-9 of the Office action. Applicants respectfully traverse the rejection for the following reasons.

To establish a *prima facie* case of obviousness, the guidelines of M.P.E.P. § 706.02(j) and case law provide three basic criteria: (1) There must be some suggestion or motivation to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the combined references must teach or suggest all claim limitations.

Examining what the collective art fairly teaches to the ordinary practitioner, it will become clear that the practitioner would not have arrived at the claimed invention. The art itself fails to provide the suggestion or motivation of the desirability of combining or modifying the references. Moreover, even if the references were taken in combination with each other, the combined art still fails to give any suggestion or motivation of doing what the inventors have done. A person of ordinary skill in the art simply would not arrive at the claimed invention without inventive effort. It is clear that the ordinary practitioner would find real distinction between the claimed invention and the cited references.

First of all, the accidental overlap with the compounds of Hatton *et al.* and Furch *et al.* due to the description of some specific compounds of the present invention in the cited art has been addressed by the current reply. Because the art compounds have been canceled from the generic compound and composition claims of the application, the Examiner's point that the references teach N-phenylpyrazole compounds that are structurally the same as the instant claimed compounds no longer applies to the case at hand.

Furthermore, the proviso, added by the present amendment, sufficiently distinguishes the instantly claimed generic invention from the cited art to evidence that Applicants' compounds are not obvious from the compounds taught by either Hatton *et al.* or Furch *et al.* It is certain that the specific compounds of Claims 10 and 26, as amended, are not found or proposed in the art. Indeed, the cited references do not name any of the species recited in Claims 10 and 26, nor does the art describe their preparation or ectoparasitidal use.

The fact that the references teach certain pesticidal N-phenylpyrazole compounds does not preclude others from creating new, useful and patentable pesticidal N-phenylpyrazole compounds. There is no question that one would need to modify the teachings in the art to arrive at the structure of the novel compounds of the present invention. Thus, in order to justify the Examiner's position, there must be adequate support in the art for the necessary structural changes to obtain the compounds of this invention. Since the isolated or combined disclosures of both Hatton *et al.* documents and Furch *et al.* do not teach or propose the required modification of their compounds, it is clear that the cited references lack the missing link that is involved and necessary to make the unique N-phenyl-3-cyclopropylpyrazole-4-carbonitrile compounds of the present invention.

Looking at the efficacy data against adult cat fleas, adult ticks and blowfly larvae on pages 18-24, the variability of the pesticidal activity proves that a little structural change can significantly impact the biological properties and potencies of the compounds. For example, test compound 30 wherein R<sub>1</sub> is NO<sub>2</sub> shows excellent activity against adult cat fleas but very weak activity against blowfly larvae in which greater concentration of compound will be needed for proper treatment. One of ordinary skill in the art could not predict the effect of any change on the pesticidal N-phenylpyrazole compounds taught in the art and would not be particularly motivated to make the changes without some teaching in the art to warrant them. Similar properties or uses to those seen in the art would not be expected from the instantly claimed compounds. Predictability cannot be based on the art. Since the art is not predictable, the cited references do not render the claimed invention obvious.

Clearly, the ordinary practitioner cannot simply come up with any efficacious N-phenylpyrazole compound or composition after just reading Hatton *et al.* or Furch *et al.*, alone or in combination. As the Applicants have demonstrated, some compounds work quite well as

ectoparasitocidal agents, while others are not nearly as efficacious. Some, in fact, appear to be of little practical value at the tested concentration range (see the lack of activity of test compounds 10, 11, 13, 15, 17, 18, 34 and 35 against blowfly larvae at the tested levels showing that these compounds will require higher doses to ascertain their effective concentrations). None of this could have been gleaned from the cited references. For example, specific test compounds 26 and 27 show excellent activity against adult cat fleas but have lesser or even no efficacy against blowfly larvae at the lower tested level of 2.0 ppm and 0.2 ppm, respectively. Equally surprising, both compounds 26 and 27 demonstrate significantly improved efficacy against blowfly larvae of 97% and 100% when the concentration is increased to 20 ppm and 2.0 ppm, respectively. Yet, by reading the broad disclosure of the cited references, the skilled artisan would never have known this. It was only the present Applicants who carefully discovered a sub-group of compounds that would work in killing biting and sucking insects.

Moreover, there is an art-recognized problem that many ectoparasitocidal compounds have lost considerable efficacy over time due to development of resistant strains of parasites. The new compounds and pour-on formulations of the present invention provide a real solution to that problem, and can keep livestock and companion animals free of disease-bearing pests.

In terms of the specific pour-on formulations of the present invention, it is submitted that the patentability considerations of Claims 24, 25, 31, 32, 34 and 35 are different from the generic composition claims that merely recite a compound and a pharmaceutically acceptable carrier (*i.e.*, Claims 1 and 26). Examined as a whole, the specific pour-on formulations of this invention are distinctive from the art products. Certainly, the bare disclosure of numerous ingredients in Hatton *et al.* or Furch *et al.* does not teach a specific pour-on formulation comprising a spreading oil, an aliphatic or aromatic hydrocarbon, mono or polyhydric alcohol, a C<sub>1</sub>-C<sub>10</sub> alkyl ketone, or a mixture thereof, in combination with the claim-recited compounds. Indeed, none of the references describe all of the claim limitations or suggest the desirability of putting these particular ingredients together in a unique pour-on formulation. Taken as a whole, the claimed pour-on formulation is neither taught nor suggested by the art.

In view of the amendment and the above remarks, Applicants respectfully ask that the rejection of Claims 1, 3-10, 24-29 and 31-35 under 35 U.S.C. § 103(a) be withdrawn and the application be held allowable.

The Examiner is encouraged to contact the undersigned attorney to discuss any outstanding issues that may have been inadvertently missed in the response.

Accordingly, it is believed that this application is now in condition for an allowance. Favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

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